

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/US2005/006569

International filing date (day/month/year)
01.03.2005

Priority date (day/month/year)
12.03.2004

International Patent Classification (IPC) or both national classification and IPC
A61N1/05

Applicant
BOSTON SCIENTIFIC SCIMED, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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Authorized Officer

Loveniers, K



**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2005/006569

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2005/006569

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	
	No: Claims	1-24
Inventive step (IS)	Yes: Claims	
	No: Claims	1-24
Industrial applicability (IA)	Yes: Claims	1-24
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item V.

1 Reference is made to the following document:

- D1: US 2001/053885 A1 (GIELEN FRANS ET AL) 20 December 2001 (2001-12-20)
- D2: US-A-4 658 835 (POHNDORF ET AL) 21 April 1987 (1987-04-21)
- D3: US-A-4 285 347 (HESS ET AL) 25 August 1981 (1981-08-25)
- D4: EP-A-0 865 800 (MEDTRONIC, INC) 23 September 1998 (1998-09-23)
- D5: US 2002/151948 A1 (KING GARY WILLIAM ET AL) 17 October 2002 (2002-10-17)

2 INDEPENDENT CLAIM 1

2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of **claim 1** is not new in the sense of **Article 33(2) PCT**.

Document D1 discloses (the references in parentheses applying to this document) (see figs. 19, 2):

A medical lead (23), comprising:

- an electrically insulative tubular membrane (125, 120) having an inner surface and an outer surface;
- a resilient spring element (S1) associated with the insulative membrane;
- at least one electrode (E1) associated with the outer surface of the insulative membrane.

2.2 For the sake of completeness, it is pointed out that also documents D2 (see figs. 4 and 5) and D3 (see figs. 2-5) take away the novelty (Art. 33(2) PCT) of claim 1.

3 INDEPENDENT CLAIM 13

3.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of **claim 13** is not new in the sense of **Article 33(2) PCT**.

Document D1 discloses (the references in parentheses applying to this document) (see fig. 19):

A medical lead, comprising:

- an electrically insulative membrane (*see fig. 19: membrane between dorsal component 125 and ventral component 120*) having a first stiffness;
- a resilient skeletal spring layer (S1) associated with the insulative membrane, wherein

the spring layer has a second stiffness greater than the first stiffness (*the function of the spring layer is to make the assembly return to its initial position. This is necessary because the pulling force of the insulative membrane when stretched is not sufficient to do this. In other words, the stiffness of the spring is greater than the stiffness of the insulative membrane*); and

- at least one electrode (E1) associated with the insulative membrane.

3.2 For the sake of completeness, it is pointed out that also documents D4 (see fig. 4A and column 4, lines 35-55) and D5 (see fig. 4A and par. 59, last sentence) take away the novelty (Art. 33(2) PCT) of claim 13 (see fig. 4a and column 4, lines 47-52).

4 DEPENDENT CLAIMS 2-12, 14-24

Dependent **claims 2-12, 14-24** do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (**Article 33(2) and (3) PCT**), because their features are already disclosed in the following passages:

- claim 2: see D1, par. 56;
- claim 3: see par. 3 of this communication;
- claims 4, 14: see D1, par. 78;
- claims 5, 9: see D1, fig. 19;
- claim 6: see e.g. D2, fig. 5;
- claims 7, 8: see e.g. D3, figs. 2-5;
- claims 10, 22: see D1, par. 71;
- claims 11, 23: see D1, figs. 1-3;
- claims 12, 24: see D1, fig. 2.
- claims 15, 16: see D1, par. 51;
- claim 17, 18: see D1, par. 56;
- claims 19, 20: see e.g. D4, fig. 4a;
- claim 21: see e.g. D5, par. 59.